No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF THE BOSTON PATENT LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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INTEREST OF THE BOSTON PATENT LAW ASSOCIATION

The Boston Patent Law Association ("BPLA") is a nonprofit professional association of approximately 1,000 attorneys and other professionals whose interests and practices are in the area of intellectual property law. Its members provide a variety of patent-related services, including patent prosecution, litigation, and licensing and serve a broad range of clients who rely on the patent system, such as inventors, businesses large and small, and universities and other research institutions. The BPLA therefore has an institutional interest in seeing that patent law develop in a clear, predictable, and coherent way in order to promote innovation and protect innovators.[1]

SUMMARY OF ARGUMENT

The BPLA believes that the patent system and its participants are best-served by clear and predictable patent laws. It is essential that all participants in the patent system understand both what the laws require and what the laws proscribe in order to effectively protect their own intellectual property and respect the intellectual property of others. This is especially true in context of collaboration with third-parties, whether it be joint development or contract manufacturing. Innovators

1. The BPLA has no financial interest in any party or the outcome of this case. This brief was neither authored nor paid for, in whole or in part, by any party. Petitioner has consented to the filing of this brief through a blanket consent letter filed with the Clerk's Office on March 13, 2018. Respondents have consented to the filing of this brief through a blanket consent filed on March 19, 2018.

need to know what conduct will or will not create a bar to obtaining patent protection. To that end, the BPLA believes the Court should grant certiorari in this case to make clear whether the meaning of "on sale" as used in 35 U.S.C. § 102(a) retains the same meaning that "on sale" had prior to the America Invents Act ("AIA"). Further, should the Court decide "on sale" has a different meaning under the AIA, the BPLA encourages the Court to provide a framework under which to analyze whether an invention is "on sale." While the BPLA takes no position on the ultimate resolution of these issues, it nonetheless believes resolving them now is critical for the predictability of law that is essential to a well-functioning patent system.

The BPLA believes this is the appropriate case for this Court to provide clear guidance on the scope of "on sale" prior art for two reasons. First, the Federal Circuit panel decision left undecided critical questions squarely raised in this case about the scope of "on sale" prior art under the AIA. Second, this is precisely the kind of case that is appropriate for review by the Court: it raises an important question of federal law that should, and only can, be settled by this Court. *See* Supreme Court Rule 10.

ARGUMENT

I. THE COURT SHOULD DECIDE WHETHER THE AIA CHANGED THE MEANING OF "ON SALE"

Prior to the AIA, 35 U.S.C. § 102 provided that "[a] person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or *on sale* in

this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102, *amended* by Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (emphasis added). Numerous cases interpreting the meaning of "on sale," as used in pre-AIA section 102, held that the existence of a sale of the invention need not be public for the sale to preclude patentability. *Helsinn Healthcare S.A. et al. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356, 1367 fn. 7 (Fed. Cir. 2017). The AIA amended the prior art provisions of section 102 to provide "[a] person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, *on sale*, or otherwise available to the public before the effective filing date of the claimed invention." 35 U.S.C. § 102(a) (emphasis added).

As made clear by the fact that the parties, the U.S. Patent and Trademark Office ("PTO"), and amici in the Federal Circuit below have taken varying positions in their briefs on whether, and how, the AIA changed the meaning of "on sale," there is substantial confusion on the effect of these AIA amendments. The district court below, in an issue of first impression, concluded that the AIA did work a substantial change in the pre-AIA definition of "on-sale." The parties vigorously contested that result in briefing before the Federal Circuit. Under some of the competing interpretations, a wholly confidential sale could be prior art, as was the case before the AIA. Other interpretations, including the district court's, would require that a sale make the details of the invention "available to the public" in order to be prior art.

Despite this confusion, the Federal Circuit panel expressly declined to decide whether the AIA changed the meaning of "on sale." *See Helsinn*, 855 F.3d at 1368. Instead, the panel concluded "that, after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *Id.* at 1371. In tailoring its holding so narrowly, the Federal Circuit panel decision provides little guidance on the scope of "on sale" prior art under the AIA. And the Federal Circuit declined to provide further guidance *en banc*. *See* Pet. App. at 2a.

Yet squarely at issue in this case is the broader question of whether the meaning of "on sale" changed under the AIA. Petitioner frames the Question Presented as the following:

> Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

Necessarily bound up with that inquiry is whether the inclusion of the phrase "or otherwise available to the public" in section 102 changed the meaning of "on sale" in any way. The Federal Circuit panel decision side-stepped this issue, cabining the decision to the facts of the case by only holding that "the AIA did not change the statutory meaning of 'on sale' *in the circumstances involved here*." *Helsinn*, 855 F.3d at 1360 (emphasis added). Further, the panel decision altogether avoids the issue of whether non-public sales constitute "on sale" prior art.

These are foundational issues in patent law. All participants in the patent system must be able to determine what constitutes prior art under the AIA. It is essential for an inventor deciding whether to file a patent application to understand what is prior art and what is not, and whether her business conduct will result in a loss of right. It is just as essential for a company determining a strategy for enforcing its patents to understand exactly what is prior art. Without this fundamental understanding, innovators cannot make reliable decisions.

Accordingly, the BPLA encourages the Court to grant certiorari and provide clear guidance on the meaning of "on sale," including, to the extent necessary, a framework for determining when an invention is "on sale" akin to the framework announced in *Pfaff*. *See Pfaff v. Wells Elecs, Inc.*, 525 U.S. 55 (1998) (holding the pre-AIA on-sale bar applies when two conditions are satisfied before the critical date: 1) the invention is subject of a commercial offer for sale and 2) the invention is ready for patenting). This Court should seize this opportunity to improve the predictability of patent law at the outset, before many district courts and patent examiners potentially reach conflicting conclusions on the effect of the AIA.

II. THIS IS THE PROPER CASE FOR REVIEW

A. This Case Presents a Statutory Interpretation Question of First Impression

"[C]ertiorari jurisdiction exists to clarify the law." *City and County of San Francisco, Calif. v. Sheehan*, 135 S. Ct. 1765, 1774 (2015). This includes the crucial function of clarifying the effects of amendments on statutes that this

Court has previously addressed. *See, e.g., TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514 (2017) (holding amendments to 28 U.S.C. § 1391 did not change the meaning of 28 U.S.C. § 1400(b) as interpreted by *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222 (1957)). And this is precisely the kind of case that presents such an opportunity. The AIA's amendments to section 102 have created confusion over the meaning of "on-sale." What was once an area of reasonably well-developed law with well-understood meaning pre-AIA is now rife with uncertainty concerning the extent to which a sale must be made public in order to constitute patent defeating "on-sale" prior art. This is an important issue of federal law that the Federal Circuit has twice chosen not to resolve, so this Court should provide guidance.

The BPLA believes the Court should seize this opportunity. Granting certiorari will provide the appropriate setting for this Court to perform a full analysis of "on sale" under the AIA and provide a clear statement on its correct interpretation. This widened inquiry is especially worthwhile here where whether the meaning of "on sale" has changed is a threshold issue. The Court's decision will either indicate that the extensive case law on this issue continues to apply (should the Court confirm that the meaning of "on sale" is unchanged) or spur lower courts to begin developing the contours of the law under the new meaning on-sale (should the Court confirm that the meaning of "on-sale" has unchanged). The Court should address this issue head on.

B. The Statute at Issue Has Multiple Plausible Interpretations

Granting certiorari is appropriate, as there are multiple, conflicting plausible interpretations of the statutory language, and the Federal Circuit panel decision leaves open which is the correct interpretation. For example, the district court below concluded that the AIA changed the meaning of "on sale" to require that the sale or offer for sale must be public. The PTO's position prior to the Federal Circuit opinion went further, stating that section 102(a) required that the sale make the invention itself public. *See* Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059, 11,075 (Feb. 14, 2013). The current petition shares this position. Finally, the Federal Circuit panel held that the AIA does not require the sale to make the invention public, but it failed to address whether the sale itself needs to be public. *See Helsinn Healthcare S.A. et al. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356, 1368-1371 (Fed. Cir. 2017).

At bottom, there is confusion over what "on sale" means after the AIA amendments. And the lack of guidance provided by the panel decision is made all the more evident by the concurrence to the Federal Circuit's denial of rehearing *en banc*, which spends thirteen pages attempting to clarify the panel's holding. *See* Pet. App. at 3a-16a. But, as it is not binding authority on any lower court, the concurrence does little to contribute consistency in interpreting this law. Given this confusion, the Court should address these competing interpretations and questions unanswered by the panel.

C. Resolution of the Underlying Questions in this Case has Broad Implications on the Patent System and Its Participants

The scope of the prior art is a foundational issue in our patent system. As such, the need for resolving the scope of "on sale" under the AIA extends far beyond this particular case and these particular parties. *Cf. City and County of San Francisco, Calif. v. Sheehan*, 135 S. Ct. 1765, 1779 (2015) (Scalia, J., concurring in part and dissenting in part) ("But it is also true that there was little chance that we would have taken this case to decide only the second, fact-bound QP.").

Leaving these issues unresolved now will materially impact all participants in the patent system. Predictability of the law is essential to a well-functioning patent system because participants adjust their behavior and investment of resources based on their understanding of the patent laws. Uncertainty regarding the most basic laws of patentability can reduce participation in the patent system.

The importance of resolving these issues, and doing so now, is most apparent as it concerns the PTO's examination of new patent applications. The PTO previously determined that the AIA did change the meaning of "on sale," concluding "[t]he phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), ***except that the sale must make the invention available to the public***." *See* Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059, 11,075 (Feb.

14, 2013) (emphasis added). Thus, based on the Federal Circuit's *Helsinn* decision, the PTO has been applying an incorrect interpretation of section 102(a) for years. The PTO, and the entire patent system, benefits from examiners applying the correct definition of "on sale" prior art. Without clear guidance from this Court on the most basic boundaries of "on sale" prior art, the PTO may allow or reject applications due to a misunderstanding of the law. Whatever the correct interpretation of "on sale" is under the AIA, it is critical that the PTO be given that guidance as soon as possible.

Further, individuals and businesses are impacted by the uncertainty. This Court has recognized the importance of "providing inventors with a definite standard for determining when a patent application must be filed." *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 65 (1998). And it has acknowledged that a murky rule "undermines the interest in certainty." *See Id.* at 65-66. Without clear guidance on the scope of "on sale" prior art, innovators will be unable to determine whether a given transaction starts the clock to file the application. And whether the exceptions of 102(b) are available is frequently determinative in whether an inventor files a patent application.

Further, without clear guidance on the scope of "on sale" prior art, businesses also cannot determine how to structure inter-company agreements in a manner that avoids creating invalidating prior art. This can lead to inefficiencies as businesses either forgo beneficial collaboration with other businesses or reduce their participation in the patent system because the uncertainty reduces the value of patents. Either result ultimately hurts the patent system's ability to promote innovation.

CONCLUSION

For the foregoing reasons, this Court should grant certiorari. The BPLA respectfully encourages the Court to take this opportunity to clarify what effect, if any, the AIA had on the meaning of term "on sale," as used in 35 U.S.C. § 102(a).

Respectfully Submitted,

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